UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ZELTIQ AESTHETICS, INC.,

Plaintiff,

v.

BTL INDUSTRIES, INC., et al.,

Defendants.

Case No. 13-cv-05473-JCS

ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION

Dkt. No. 18

I. INTRODUCTION

Plaintiff Zeltiq Aesthetics, Inc. ("Zeltiq") filed this action against Defendants BTL Industries, Inc. and Saturn Consulting LLC dba Monarch Laser Services ("Defendants"). Zeltiq alleges that Defendants falsely advertised that a medical device manufactured by BTL was approved by the federal Food and Drug Administration ("FDA") to be used for fat reduction and body contouring. Zeltiq asserts claims under the Lanham Act, 15 U.S.C. § 1125, and claims for unfair competition under California's Business and Professional Code § 17200 and Massachusetts General Laws ch. 93A § 2. Zeltiq filed a Motion for Preliminary Injunction ("Motion"). The Court held a hearing on the Motion on March 14, 2014, at 9:30 a.m. For the reasons explained below, the Motion for Preliminary Injunction is DENIED.[1]

II. BACKGROUND

A. FDA's Premarket Approval and 510(k) Clearance

In 1976, Congress amended the federal Food, Drug, and Cosmetic Act ("FDCA"), which previously only regulated food and drugs, with the Medical Device Amendments ("MDA"), 90

[1] The parties have consented to the jurisdiction of the undersigned magistrate judge pursuant to 28 U.S.C. § 636(c).

Stat. 539, 21 U.S.C. § 301. The MDA "classifies medical devices in three categories based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). As explained by the Supreme Court in *Medtronic*:

> Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." § 360c(a)(1)(B). Finally, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. § 360c(a)(1)(C).

Id. at 476-77. While "Class III devices must complete a thorough review process with the FDA before they may be marketed," *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001), Class I and II devices only need to submit a " 'premarket notification' to the FDA, in accordance with the less burdensome '510(k) process.' " *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010) (quoting *Medtronic*, 518 U.S. at 477-79).

"Under the 510(k) process,[2] if the Class II device is deemed 'substantially equivalent' to a pre-existing device with prior clearance, 'it can be marketed without further regulatory analysis.'"[3] *Id*. (citing *Medtronic*, 518 U.S. at 478; 21 U.S.C. § 360(k); 21 C.F.R. § 807.100). " '[S]ubstantial equivalence"' means, with respect to a device being compared to a predicate device, that the device has the *same intended use* as the predicate device…." 21 U.S.C. § 360c(i)(1)(A); *see also* 21 C.F.R. § 807.100 ("FDA will determine that a device is substantially equivalent to a predicate device … [if, *inter alia*, t]he device has the *same intended use* as the predicate device.") (emphasis added).

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[2] The process is known as the "§ 510(k) process" because that was "the section in the original Act." *Medtronic*, 518 U.S. at 478.

[3] "Unlike premarket approval, 510(k) clearance 'does not in any way denote official approval of the device.' " *PhotoMedex*, 601 F.3d at 925 n. 3 (quoting 21 C.F.R. § 807.97).

B. Zeltiq's CoolSculpting System

Zeltiq manufactures and markets a medical device known as CoolSculpting. Declaration of Patricia Altavilla ("Altavilla Decl.") ¶ 6. CoolSculpting is designed to reduce the temperature of fat cells in the treated area, which is intended to cause fat cell elimination through a natural biological process known as "apoptosis" without causing scar tissue or damage to the skin, nerves or surrounding tissue. *Id.* ¶ 7. CoolSculpting is clinically proven to reduce fat bulges in a sixty-minute procedure. *Id.*

Zeltiq's CoolSculpting system has been cleared by the FDA for cold-assisted lipolysis of the flank, or "love handles" and the abdomen. *Id.* ¶ 6. Zeltiq states that it "developed its CoolSculpting technology for a novel indication," and therefore, "submitted clinical studies and other data to FDA to obtain 510(k) clearance for CoolSculpting." Altavilla Decl. ¶ 8. Zeltiq states that it undertook the expensive endeavor of obtaining 510(k) clearance because clearance of a device for treatment of body fat conveys instant and substantial credibility to the device. *Id.*

As a result of its investment to secure FDA clearance, CoolSculpting has become the leading noninvasive medical device for reduction of body fat. *Id.* ¶ 9. In its most recent quarterly filing, Zeltiq reports having sold over 1,900 CoolSculpting devices and over 500 in the twelve months between September 30, 2012 and September 30, 2013. Declaration of Jeffrey E. Faucette ("Faucette Decl.") ¶ 2, Exh. A at 19. Zeltiq also reports having generated over $75 million in revenue in the nine months ending in September 30, 2013. *Id.* In a preliminary full year report, Zeltiq noted that its revenue increased approximately 91% in one year. Faucette Decl., Exh. G.

C. BTL's Vanquish Device

Defendant BTL Industries, Inc. ("BTL") is the United States distributor for BTL Industries, which is a worldwide manufacturer of medical devices. Declaration of Michael Besse ("Besse Decl.") ¶ 2. BLT Industries has offices in over thirty countries and is one of the world's major manufacturers of medical devices in medical aesthetics and other areas. *Id.* ¶¶ 2-3.

BTL submitted to a notice of intent under § 510(k) to market a device that it called "BTL Elite." Altavilla Decl. ¶ 12. Zeltiq states that, like the predicate devices identified in BTL's 510(k), the BTL Elite was designed to deliver heat to muscle tissue. *Id.* BTL asked for FDA

clearance to market its device for

> use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

Altavilla Decl. ¶ 12, Exh. 1. The FDA send BTL a 510(k) letter of approval clearing the BTL Elite for those proposed uses. *Id*.

BTL now manufactures and markets a device it calls "Vanquish." Zeltiq does not contend that Defendants unlawfully market Vanquish because it differs from the technology or design for the BTL Elite. Rather, Zeltiq argues that Defendants unlawfully market the Vanquish device because it is promoted for fat reduction and body contouring, which not a *use* that has been cleared through the 510(k) process for the BTL Elite.

The "Instructions for Use" or "IFU" for the Vanquish device tracks the indications for use that the FDA has cleared for the BTL Elite: the treatment of muscle aches and pains. Altavilla Decl. ¶ 33, Exh. 20. The IFU for the Vanquish is found within the "Operator's Manual" that is provided to every physician who purchases the device. Declaration of Marcel Besse ("Besse Decl.") ¶ 14; Altavilla Decl. ¶ 33, Exh. 20. In the United States, BTL only sells the Vanquish device to physicians and it cannot be purchased by consumers. Besse Decl. ¶ 13.

D. Defendants' Promotion of Vanquish

Zeltiq contends that, despite having no FDA clearance to market and distribute Vanquish for use in fat reduction and body contouring, Defendants have *only* promoted Vanquish for this unapproved use. Zeltiq states that there is not a single instance in which Defendants promoted Vanquish for the treatment of muscle aches and spasms, which is the only purpose for which it was cleared. Altavilla Decl. ¶ 32. Zeltiq also accuses Defendants of promoting Vanquish exclusively for fat reduction and body contouring while touting the device as "FDA-cleared" without explaining the limits of the FDA's clearance. Zeltiq asserts this is an attempt to mislead physicians into believing that Vanquish is FDA-approved for fat reduction.

Defendants do not dispute that, in 2013, they promoted Vanquish for fat reduction−which

Defendants admit is an "off-label use." Nor do Defendants dispute that they have only intended to promote Vanquish for fat reduction. Indeed, BTL's trademark registration describes Vanquish as a "[b]ody treatment device using heating and cooling for fat cell reduction." Declaration of Thomas Hanrahan ("Hanrahan Decl."), Exh. 22. Defendants contend, however, that they no longer promote Vanquish in the United States for any off-label use, and further contend that they never directly or indirectly represented that Vanquish has received FDA clearance for fat reduction or body contouring. Besse Decl. ¶ 14.

1. Defendants' Promotion of Vanquish to Physicians at Medical Conferences and Workshops

In the spring of 2013, BTL launched Vanquish at three medical conferences: a meeting in Boston of the American Society for Lasers Medicine and Surgery, a meeting in Miami of the American Academy of Dermatology, and a meeting in New York of the American Society for Aesthetic Plastic Surgery. Altavilla Decl. ¶ 15. Plaintiff states that at these conferences, BTL did not talk about using Vanquish for its cleared use—the treatment of aches and pains. Rather, BTL promoted Vanquish as able to "reduce fat." *Id*.

Zeltiq states that after the initial launch of Vanquish, Defendants hosted several workshops in the United States in which they promoted the use of Vanquish for fat reduction. For instance, on September 29, 2013, Defendants held a workshop in Los Angeles at the Westin Hotel at the Los Angeles International Airport. Altavilla Decl. ¶ 27; Declaration of Kevin Meyers ("Meyers Decl.") ¶ 5. A similar event was held in Carlsbad, California in early October 2013. *Id*. Zeltiq states that at these events, Defendants distributed literature depicting Vanquish as a product for body shaping and contouring. *Id*. The main presenter at the Los Angeles workshop focused his remarks on fat reduction and body contouring using BTL's Vanquish device and other products. Altavilla Decl. ¶ 27; *see also* Meyers Decl. ¶ 5. Defendants state that at these workshops, they did not represent that the Vanquish device had FDA clearance for fat reduction or body contouring. Meyers Decl. ¶ 6.

In October 2013, BTL was one of the sponsors at the annual meeting for the American Society for Dermatologic Surgery. Altavilla Decl. ¶ 31. In connection with this meeting, BTL

invited doctors to a private demonstration of the Vanquish device with the following invitation: "Join us for a private demonstration of a newly FDA cleared technology … The only complete solution for non-invasive body shaping." *Id*., Exh. 19. Zeltiq states that this invitation is misleading, as it implies that the Vanquish device is FDA approved for body shaping.

Defendants claim that in 2014, there have been no company-sponsored events or presentations in the United States regarding the use of Vanquish for fat reduction. Besse Decl. ¶ 12; Meyers Decl. ¶ 7. Zeltiq submitted evidence which shows that BTL was and is a planned exhibitor for two events in California in February and April of 2014. Supplemental Declaration of Thomas Hanrahan ¶¶ 2-3, Exh. 23-24. The exhibitor lists show that BTL planned to display three aesthetic devices, including the Vanquish device. *Id*. The Vanquish device is not described in these 2014 exhibitor lists as a fat reduction device. Rather, Vanquish is obscurely described as delivering "sub-cutaneous heating for body treatment based on induced apoptosis using a contract-free operator-monitored clinical approach." *Id*.

2. Defendants' Promotion to the End Consumer

Despite the fact the Vanquish device may only be sold to physicians, Zeltiq has submitted evidence that BTL has also promoted the fat reduction qualities of the Vanquish device to the end consumer. For instance, on the cover of the summer issue of *New You*, a promotional message for Vanquish states that the technology "is proven to destroy fat cells." Altavilla Decl. ¶ 19, Exh. 3.

Zeltiq also states that Vanquish is featured in a March 7, 2013 article in *Allure* magazine that describes Vanquish as "a new fat-reduction machine." Altavilla Decl. ¶ 20, Exh. 4. The article also notes that there are several other devices are "awaiting FDA approval," and then comments that Vanquish "is approved for deep-tissue heating, a known method for targeting fat, and has minimal side effects." *Id*. BLT states that this article was not published in *Allure* magazine as Zeltiq claims, but rather posted on a blog maintained by an *Allure* reporter. Besse Decl. ¶ 6. BLT states that it was only asked to supply a photograph for this article, and had no control over the content or publication of the blog post. *Id*.

Zeltiq also claims that BTL recruited certain physicians to promote Vanquish as a fat reduction device despite its lack of FDA clearance for fat reduction. Altavilla Decl. ¶ 16. Zeltiq

states that in April 2013, coincident with the launch announcement of Vanquish, a physician in Nevada wrote an article about Vanquish on www.vanquishfat.com. On that website—which does not appear to be for a medical audience, the physician states that he had "heard about a new, fat zipping device that's about to receive FDA approval." Altavilla Decl. ¶ 16, Exh. 2. Zeltiq also states that this same physician created a "Vanquish Fat" Facebook page and claimed that "Vanquish Melts Fat With No Pain." Altavilla Decl. ¶ 16, Exh. 2. Unlike other websites discussed below, Defendants do not submit any evidence in an attempt to disassociate from these promotions.

3. BTL's Official Websites

To promote Vanquish online, there is both a "United States" website at www.bltvanquish.com and a "Non-United States" website (which used to be called the "International" website) at www.bltvanquish.com/en/vanquish.html. Altavilla Decl. ¶ 24; Besse Decl. ¶ 8. BTL states that it only controls the content of the United States website. Besse Decl. ¶ 8. According to BTL, the content of the non-United States website is controlled overseas by BTL Industries and is directed at a worldwide audience. *Id*.

Currently, only the non-United States website explicitly promotes the Vanquish device for fat reduction. Altavilla Decl. ¶ 25d, Exhs. 9-12. According to Zeltiq, this was not always the case. Zeltiq states that the United States website used to promote Vanquish for fat reduction by displaying a video clip from a Texas doctor who declared that the Vanquish device "shrinks fat cells," and by quoting a number of other U.S. doctors extolling the benefits of Vanquish as a fat reduction device. Altavilla Decl. ¶ 17. A printout depicting BTL's original website is not in evidence. Zeltiq states that BTL's original website omitted any disclosure of the scope of FDA clearance, and did not indicate that Vanquish was not FDA approved for fat reduction. Altavilla Decl. ¶ 25a.

According to Zeltiq, after the filing of the Complaint in this action, BTL modified the content of its United State website. Altavilla Decl. ¶ 25c; *see also* Besse Decl. ¶ , Ex. A (printout of current website). Defendants state that in December 2013, BTL contracted with Michail M. Prankratov to provide training to BTL regarding the regulations governing marketing of aesthetic

medical devices. Declaration of Michail M. Pankratov ("Pankratov Decl.") ¶ 3.

The current United States website does not explicitly promote Vanquish for fat reduction or body contouring. Rather, it describes Vanquish as "a revolutionary selective radiofrequency system" that "delivers a non-invasive solution with unparalleled efficacy" and "is the first and only non-invasive body treatment finally integrating all the most desired features." *Id*. The website states that "Vanquish is FDA cleared for deep tissue heating." *Id*. Fine print at the bottom of the website describes the specific intended uses of Vanquish:

> In the US Vanquish is indicated for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions, such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

Id. The website also notes the following "Important Limitations":

> The information on this website is intended for US medical professionals only. Vanquish is not cleared for the treatment of adipose tissue. Treatment with Vanquish is not intended to substitute for usual standard of car for adipose tissue treatment regimes.

Id. "Adipose tissue" is the anatomical term for body fat. Altavilla Decl. ¶ 25c.

Zeltiq states that despite the purported separation of the two websites, the non-United States website−both in its prior and modified form−is actually intended to promote the Vanquish device to a United States audience. For instance, Zeltiq notes that BTL sent invitations for physicians to attend a VIP Open House and Exhibit Display in Boston and New York, and only listed the address for the non-United States website on the invitation. Altavilla Decl. ¶ 24, Exh. 7. Moreover, until recently, the largest and boldest text on the United States website was a link in the middle of the page that stated, "Go to Non-US Website." Altavilla Decl. ¶ 25b-c, Exh. 8; Besse Decl., Exh. A. The United States website contains hardly any information about Vanquish (the majority of the text is quoted above). By contrast, the non-United States website features various pages and links that promote Vanquish for fat reduction, including a "buzz" page that links magazine articles and videos quoting United States doctors who promote Vanquish for fat reduction. Altavilla Decl., Exhs. 9-13.

In addition, the "international" website used to include a page entitled "Scientific Seminars for Physicians," which is now entitled "Events" on the "non-United States" website. Altavilla Decl. ¶ 25h. An earlier printout of this page lists five conferences that were to take place in September and October of 2013 in New York City, Los Angeles, San Diego, Oklahoma City and San Francisco. *Id*., Exh. 14. Another printout of this page lists nine conferences that are to take place in 2014. *Id*., Exh. 15. The conferences planned for 2014 are both inside and outside the United States, as the evidence shows that they are planned to take place in Bangkok, Maui, Paris, Colorado, Monte Carlo, San Francisco, Arizona, Germany, Hong Kong and Singapore. *Id*.

4. Other Websites Promoting Vanquish

Zeltiq directs the Court to a number of other websites promoting Vanquish for fat reduction, but for these websites, Defendants deny involvement or control. For instance, Zeltiq notes that there used to be a Facebook page entitled "Vanquish by BTL" which claimed that Vanquish "Zaps Fat With No Pain." Altavilla Decl. ¶ 22, Exh. 5. BTL states, however, that it did not create this Facebook page and believes it was created by a Malaysian company. Besse Decl. ¶ 7. Under the contact information of the Facebook page, a Malaysian email address is listed. Altavilla Decl., Exh. 5. The Facebook page is not currently available.

Zeltiq also points to three websites maintained by physicians promoting Vanquish for fat reduction. *Id*. ¶ 18. A plastic surgeon from Georgia writes on his website: "If you have been looking for a painless and non-invasive procedure for permanent fat removal and minimal risks, look no further than Vanquish…." *Id*. A doctor in Colorado announces on his website that he is "1 of Only 5 Physicians in the Country to Offer the New Vanquish Fat Reduction Treatment." *Id*. Another doctor from Atlanta claims on his website that "Vanquish is a new, revolutionary procedure in permanent fat reduction." *Id*. BTL states that it never asked anyone to create these websites and has no control over these internet postings. Besse Decl. ¶ 5.

Zeltiq also states that BTL maintains the website www.aestheticmarketingshore.com where physicians can purchase printed marketing brochures and in-office banners to promote Vanquish for fat reduction. Altavilla Decl. ¶ 29, Exh. 18. However, BTL states that this website is an independent source of marketing materials for various medical devices including Vanquish, and

there is no corporate relationship between BTL and the owners of this website. Besse Decl. ¶ 10. BTL states that it does not share revenues generated from the sales of these marketing materials. *Id*.

Zeltiq also states that recently, another website has begun to promote Vanquish for fat removal: http://vanquishfatremovalclinics.com/. Altavilla Decl. ¶ 34. BTL again claims that it does not own this website or have any control over it. Besse Decl. ¶ 14. The website lists the clinics around the country which offer the Vanquish device as a method for fat reduction. *Id*. The website also includes links to two video clips−according to Zeltiq, these are the same video clips that were deleted from BTL's original website. *Id*. In one of the video clips, Dr. Andrew Campbell is interviewed by the hosts of The Morning Blend on Fox News. When asked whether Vanquish is safe to use, Dr. Campbell responds as follows:

> This is exceptionally safe. The FDA basically is there to provide safety, it is not so much there to provide efficacy. *So when they do these FDA approval studies, the number one, two and three thing they are looking at is safety, and this is exceptionally safe*. They – even in the animal models, they looked at every part of the animal to ensure that there was no damage to anything other than the fat.

Zeltiq claims that the reference to "FDA approval studies" is clearly misleading, as it suggests that the FDA has approved Vanquish for the purpose for which it is being promoted.

5. Physicians' Understanding of the Scope of FDA Clearance

Both parties have submitted declarations by physicians in support of their respective positions regarding whether Defendants' conduct had a tendency to mislead physicians. Zeltiq submitted the Declaration of Dr. Jill Waibel, who recognizes that physicians use medical devices for a treatment that the FDA did not evaluate (often called an "off-label use"), but states that "off-label" use generally develops only *after* physicians have had experience with the new device for its approved use. Declaration of Jill Waibel ("Waibel Decl.") ¶ 5. Waibel states that when a manufacturer promotes a new device in the early stages after device is launched, physicians presume that the new device has been approved by the FDA for the use that the manufacturer is promoting. *Id*. Dr. Waibel further states that she is influenced by other physicians that promote the Vanquish device and make "no mention of the approved use" especially "in the early

commercialization of a medical device when little other information in publically available." *Id.* ¶ 6.

Defendants submitted declarations from two other physicians: Robert Weiss, M.D. and Rutlege Forney, M.D. Dr. Forney writes in his declaration that understanding the official FDA clearances for an aesthetic device is important when making a decision to purchase a new device. Declaration of Rutledge Forney ("Forney Decl.") ¶ 3. Dr. Forney states that both the CoolSculpting and Vanquish devices cost approximately $80,000 to $90,000, and thus represents a significant capital expense in his practice. *Id.* ¶ 4. Both Dr. Forney and Dr. Weiss state that, prior to their purchase of the Vanquish device for their respective practices, they were made aware of the scope and limits of the FDA clearance. *Id.* ¶ 8; Declaration of Robert Weiss ("Weiss Decl.") ¶ 6.

E. The Complaint

Zeltiq asserts four causes of action in the Complaint. The first cause of action arises under Lanham Act, 15 U.S.C. § 1125(a), which prohibits, *inter alia*, false or misleading statements in connection with the marketing of goods. The other three causes of action arise under California's and Massachusetts's unfair competitions laws. Zetiq asserts that Defendants' misleading and deceptive advertising is a violation of California's Business and Professions Code § 17200 (the "UCL") as well as Massachusetts General Law ch. 93A § 2. Zeltiq asserts another cause of action under the UCL for Defendants' allegedly unlawful conduct in violation of California's Sherman Act, which mirrors the requirements under the FDCA.

III. DISCUSSION

A. Legal Standard − Motion for Preliminary Injunction

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Irreparable harm must be likely−it is no longer sufficient to grant a preliminary injunction upon a mere showing of a "possibility" of irreparable harm when the other factors weigh heavily in favor of the plaintiff. *Alliance for the*

Wild Rockies v. Cottrell, 632 F.3d 1127, 1132 (9th Cir. 2011). Nonetheless, the Ninth Circuit still evaluates the likelihood of success on such a "sliding scale." *Id.* A preliminary injunction may be warranted upon a showing of "*serious questions* going to the merits" as well as "a hardship balance that tips *sharply* toward the plaintiff," so long as the plaintiff is likely to suffer irreparable harm and the injunction is in the public interest. *Id*. (emphasis added).

B. Whether Zeltiq is Likely to Succeed on the Merits of its Claims[4]

1. Deceptive Advertising in Violation of the Lanham Act and Unfair Competition Laws

The gravamen of Zeltiq's Complaint is that Defendants' promotion of the Vanquish device is false and misleading in violation of the Lanham Act, and California and Massachusetts unfair competition law. As both parties recognize, the Ninth Circuit "has consistently held that state common law claims of unfair competition and actions pursuant to California Business and Professions Code § 17200 are 'substantially congruent' to claims made under the Lanham Act." *Cleary v. News Corp.*, 30 F.3d 1255, 1262-63 (9th Cir. 1994) (citations omitted). Under the Lanham Act, Defendants are prohibited from making a "false or misleading representation of fact" which "is likely … to deceive…." 15 U.S.C. § 1125(a)(1)(A). Under California's UCL, the test is

[4] Defendants argue that Zeltiq's claims fail to the extent they are preempted or conflict with the FDA's exclusive jurisdiction to enforce the FDCA. Although this argument raises serious issues in this case, they are more appropriately dealt with at the dispositive motion stage based on a full record. In any event, the preemption argument here does not appear to bar *all* claims raised. First, at the hearing on this Motion, counsel for Defendants conceded that Zeltiq's claims are not preempted and do not conflict with the FDCA to the extent Zeltiq can show that there was a false or misleading representation that the Vanquish device is FDA cleared for fat reduction. *See PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010) ("If, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted.").

Second, based on the evidence submitted at this time, the Court would distinguish this case from the Ninth Circuit's decision in *PhotoMedex*. The Lanham Act claim in *PhotoMedex* was based on the contention that a marketed laser varied enough from a FDA cleared laser so as to require new 510(k) clearance. Because the parties disputed whether new 510(k) clearance for the laser was required, the court found that deciding the Lanhan Act claim would require interpreting provisions of the FDCA, and would usurp the FDA's exclusive authority to enforce the FDCA. In this case, by contrast, Defendants do not dispute that they promoted the Vanquish device for a use that is not FDA cleared. Accordingly, the Court need not interpret provisions of the FDCA to decide the Lanham Act and analogous state law claims.

whether Defendants engaged in any "unfair, deceptive, untrue or misleading advertising," California Business & Professions Code § 17200, that was " 'likely to deceive' the reasonable consumer to whom the practice was directed." *South Bay Chevrolet v. General Motors Acceptance Corp.*, 72 Cal.App.4th 861, 878 (1999). The "ultimate test" in both cases is whether the consumers of the good are "likely to be deceived…." *Acad. of Motion Picture Arts & Sciences v. Creative House Promotions, Inc.*, 944 F.2d 1446, 1457 (9th Cir. 1991) (internal quotations omitted); *see also Spalding Sports Worldwide, Inc. v. Wilson Sporting Goods Co.*, 198 F.Supp.2d 59, 64 (D. Mass. 2002) (considering the false advertising claim under Massachusetts General Law ch. 93A together with the Lanham Act claim). Accordingly, the following discussion considers the likelihood of success on the merits of Plaintiff's first, third and fourth causes of action.[5]

When asserting a claim under the Lanham Act, a plaintiff may establish the "falsity" of the advertisement in one of two ways. *Southland Sod Farms*, 108 F.3d at 1139. A "plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers." *Id.* As Zeltiq recognizes, different evidentiary burdens may correspond to statements that are "literally false," and those that are "literally true" but likely to mislead or confuse consumers. The difference is that "[a] literally false statement may violate Section 43(a) 'without evidence of consumer deception,' while an implied falsehood may require some extrinsic evidence that the challenged statement has a tendency to mislead or confuse consumers." Motion at 14 (quoting *Mut. Pharm. Co. v. Ivax Pharm., Inc.*, 459 F.Supp.2d 925, 933 (C.D. Cal. 2006) (citations omitted)). This is the rule adopted by most circuits. *See e.g., Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 497 (5th Cir. 2000) ("if the statements at issue are either ambiguous or true but misleading, the plaintiff must present evidence of actual deception"). The Ninth Circuit has held that "[w]here a statement is not literally false and is only misleading in context, … proof that the advertising

[5] Zeltiq's second cause of action regarding alleged "unlawful" conduct in violation of California's UCL is based on specific violations of California's Sherman Act, and is therefore distinct from Plaintiff's claim under the Lanham Act claim relating to misleading advertising. The likelihood of success on this claim is discussed below.

actually conveyed the implied message and thereby deceived a significant portion of the recipients becomes critical." *William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995).

Zeltiq has not presented evidence of any literally false statement. In response to Defendants' argument that Zeltiq has failed to produce such evidence, Zeltiq points to two items. Reply at 13. The first is the invitation BTL invitation sent to doctors inviting them to attend a demonstration of the Vanquish device. The invitation reads: "Join us for a private demonstration of a newly FDA cleared technology … The only complete solution for non-invasive body shaping." Altavilla Decl. ¶ 31, Exh. 19. This invitation is not *literally* false because the FDA issued a 510(k) clearance for the "technology" that was to be demonstrated by clearing the BTL Elite. Second, Zeltiq directs the Court to BTL's website, which still states that the Vanquish device is cleared by the FDA "for deep tissue heating." Altavilla Decl., Exh. 8; Besse Decl., Exh. A. This statement, however, is *literally true*−Vanquish is cleared by the FDA "for deep tissue heating"−and Zeltiq recognizes as much.

In an attempt to avoid the evidentiary requirements for a misleading statement as opposed to "literally false statement" under the Lanham Act, Zeltiq contends that these statements are "literally false by necessary implication." Reply at 14 (quoting *Southland Sod Farms*, 108 F.3d at 1139 (A "plaintiff may show that the statement was literally false, either on its face *or by necessary implication*….") (emphasis added) (citing *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 946-47 (3d Cir. 1993))). In *Castrol*, the Third Circuit cited the following example of a statement that is "literally false by necessary implication" from an advertisement at issue in a district court case:

> Robot-Coupe: 21
> Cuisinart: 0
>
> When all 21 of the three-star restaurants in France's Michelin Guide choose the same professional model food processor, somebody knows the score-shouldn't you?

Castrol Inc., 987 F.2d at 946 (citing *Cuisinarts, Inc. v. Robot-Coupe Int'l Corp.*, No. 81-0731, 1982 WL 121559, *2 (S.D.N.Y. June 9, 1982)). The advertisement above does not literally say that all twenty-one restaurants chose to buy the Robot-Coupe over the Cuisinart, but that is necessarily implied from what is said. In this case, Zeltiq has submitted no evidence of statements

that necessarily imply the Vanquish device is FDA cleared for fat reduction and body contouring. *Cf. Castrol Inc.*, 987 F.2d at 946; *Cuisinarts*, 1982 WL 121559, *2.

Zeltiq also argues that Defendants told "half-truths" when stating that the Vanquish device was a "newly FDA cleared technology," and that was FDA cleared "for deep tissue heating." Reply at 13-14 (citing Altavilla Decl., Exhs. 8, 19). *Id*., Exh. 8. Zeltiq contends that by telling such "half-truths," Defendants had a duty to speak the whole truth−that the Vanquish device was not FDA cleared for fat reduction and body contouring. Nevertheless, Zeltiq does not cite one case in which a "half-truth" constituted a literally false statement under the Lanham Act or state unfair competition law. The only cases cited by Zeltiq address claims for *common law fraud* under California and Oregon law. *See Meade v. Cedarapids, Inc*., 164 F.3d 1218, 1222 (9th Cir. 1999) (addressing fraud claim under Oregon law); *Whiteley v. Philip Morris Inc*., 117 Cal.App.4th 635, 675 (2004); *Randi W. v. Muroc Joint Unified School Dist.*, 14 Cal.4th 1066, 1082 (1997).

Unlike claims for common law fraud, the Lanham Act is "not limited to literal falsehoods; it extends to false representations made by implication or innuendo." *Cook, Perkiss & Liehe, Inc. v. N. California Collection Serv. Inc.*, 911 F.2d 242, 245 (9th Cir. 1990). In addition to "literally false statements," a plaintiff can prevail on a Lanham Act claim through a statement that is "literally true but likely to mislead or confuse consumers." *Southland Sod Farms*, 108 F.3d at 1139. Similarly, claims for unfair competition based on fraudulent conduct are distinct from claims for ordinary fraud because a "'fraudulent' representation may include a false statement, or one which, though strictly accurate, nonetheless has the likely effect of misleading or deceiving the public." *Garcia v. Sony Computer Entm't Am., LLC*, 859 F.Supp.2d 1056, 1062 (N.D. Cal. 2012). Thus, the concept of "half-truths" that has developed within the doctrine of common law fraud may also be actionable under the Lanham Act and State unfair competition laws. Nevertheless, such "misleading half-truths" (as they are referred to in the cases cited above) would be "literally true" statements that are "misleading" because the representations in themselves are not literally false.

Although Zeltiq failed to present evidence of any literally false statements, Zeltiq did present evidence of promotions that could misleadingly imply that Vanquish is FDA cleared for

fat reduction. Since the launch of Vanquish, Defendants have *only* promoted the device for use in fat reduction−despite the fact this is not a FDA cleared use. In some of the promotional material, Defendants even make a brief reference to "FDA clearance" without disclosing the limitations of such clearance. *See* Altavilla Decl. ¶¶ 13, 16, 20 Exhs. 2, 4, 19. In light of the fact Vanquish has only been promoted for fat reduction, such references to FDA clearance obscures the true scope of such clearance. Moreover, the fact Defendants alluded to FDA clearance in their promotional materials implies that FDA clearance is a material factor which influences physicians to buy the device.

Nevertheless, Zeltiq did not submit any evidence to show that any physician was actually deceived by Defendants' promotions of the Vanquish device.[6] Zeltiq only submitted evidence to show that when a medical device is promoted in the early stages after it is launched, physicians will presume that the device is FDA cleared for the purpose for which it is promoted. Waibel Decl. ¶ 3. According to Dr. Waibel, this is because "off-label" use of a medical device generally only develops *after* physicians have had experience with the new device for its approved use. *Id.* ¶ 5. Thus, Zeltiq believes that because Defendants were marketing the Vanquish device for fat reduction so early after its initial launch, physicians were misled into believing the Vanquish device is FDA cleared for fat reduction.

At best, Zeltiq's evidence shows that physicians in general presume the Vanquish device is FDA cleared for fat reduction because it was marketed for that use in the early stages after its launch. While that constitutes some evidence of deception, it is only a general claim of deceptive impact. In the face of Defendant's evidence on this subject, Zeltiq presents no evidence that physicians who actually purchase the Vanquish device believed it was FDA cleared for this purpose. *See Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228-29 (3d Cir. 1990) (plaintiff "cannot obtain relief by arguing how consumers *could* react; it must show how

[6] Defendants submitted two declarations from physicians who wrote that when they purchased the Vanquish device, they understood that it was not FDA cleared for use in fat reduction. *See* Forney Decl. ¶ 8; Weiss Decl. ¶ 6.

consumers *actually do* react"). Defendants' evidence shows that the Vanquish device costs approximately $80,000 to $90,000. Forney Decl. ¶ 4. The only individuals eligible to purchase the device are physicians. Besse Decl. ¶ 13. There is evidence in the record which shows that at least one group of physicians decides to purchase such an expensive medical device only after fully evaluating the device's efficacy and safety for patients and understanding the official FDA clearances. *Id*. ¶ 3. In light of the high cost of the Vanquish device, as well as the fact the only purchasers of the Vanquish device are physicians, Zeltiq is not likely to be able to prove that physicians who purchase the Vanquish device would be deceived into believing the device is FDA cleared for fat reduction.

Accordingly, Zeltiq has not demonstrated that it is likely to prevail on the merits of any of its Lanham Act claim or the analogous state law unfair competition claims based on false advertising. Nevertheless, the Court finds that Zeltiq has raised *serious questions* going to the merits of such claims.

2. *Unlawful Conduct in Violation of California's UCL*

In addition to Zeltiq's claims based on allegations of false and misleading advertising, Zeltiq asserts a separate claim under the "unlawful" prong of California's UCL based on allegations of specific violations of California's Sherman Act. First, Zeltiq alleges that BTL sold and distributed the Vanquish device without 510(k) clearance in violation of California Health and Safety Code § 111550. Section 111550 provides, in pertinent part, that "[n]o person shall sell, deliver, or give away any … new device unless … [i]t is … [a] device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k))…." Cal. Health & Safety Code § 111550(a)(3). Applied to this case, the statute would prohibit the sale of the Vanquish device had it not received 510(k) clearance. Zeltiq's problem, however, is that the Vanquish device *has* received 510(k) clearance. *See* Altavilla Decl., Exh. 1.

Zeltiq maintains that Defendants violated § 111550 by marketing Vanquish for a *use* not included in the 510(k) clearance. Zeltiq claims that "the text of Section 111550 makes plain that the relevant approval is use-specific." Motion at 18. The Court disagrees. The relevant provision of § 111550 falls under subsection (a), which provides the option for a manufacturer to sell a

device after receiving 510(k) clearance. Zeltiq quotes language from subsection (b) of the statute—which relates *to premarket approval* for Class III devices—to argue that the 510(k) clearance is only valid to the extent the device is sold for use "under the conditions prescribed, recommended, or suggested in the … advertising of the new drug or device." Cal. Health & Safety Code § 111550(b)(1). This quote is taken out of its context. The Vanquish device had 510(k) clearance prior to being sold in California. Accordingly, the Court finds that Plaintiff is not likely to show a violation of § 111550.

Zeltiq also bases the UCL-unlawful conduct claim on the allegation that BTL violated the Sherman Act by "misbranding" the Vanquish device. *See* Cal. Health & Safety Code § 111440 ("It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug that is misbranded."); *Id*. § 111445 ("It is unlawful for any person to misbrand any drug or device."); *see also id.* § 111450. Section 111375 of the Code provides the definition of 'misbranding':

> Any drug or device is misbranded unless *its labeling* bears all of the following information:
>
> (a) *Adequate directions for use*.
>
> (b) Such adequate warnings against use in pathological conditions or by children where its use may be dangerous to health.
>
> (c) Adequate warning against unsafe dosage or methods or duration of administration or application.
>
> Warnings shall be in a manner and form as are necessary for the protection of users.

Cal. Health & Safety Code § 111375 (emphasis added). The implementing regulations of the FDCA define "[a]dequate instructions for use" as "directions under which the layman can use a drug safely and *for the purposes for which it is intended*." 21 C.F.R. § 201.5 (emphasis added).

Zeltiq argues that the Vanquish device is misbranded because its labeling fails to include "adequate directions for use" in fat reduction procedures. In light of the fact the FDCA regulations require instructions to be catered to "the purposes for which [the device] is intended," 21 C.F.R. § 201.5, Zeltiq raises an interesting argument. Nevertheless, § 111375 specifically refers to the device's "labeling" as the source of any potential misbranding. Evidence in the record shows that whenever the Vanquish device is sold, the purchaser is given the "Operator's Manual," which includes the "Instructions for Use" detailing the FDA cleared uses of the device

and providing directions for such uses. Besse Decl. ¶ 14. Zeltiq has not cited any authority to suggest that a device may be "misbranded" by virtue of its overall promotional practices as opposed to the more obvious source of "labeling": the Instructions for Use in the Operator's Manual. Accordingly, while the Court finds that Zeltiq has raised serious questions going to the merits of this issue, the Court does not find that Zeltiq is likely to prevail on this claim.

C. Whether the Balance of Harships Tips Sharply in Zeltiq's Favor

Having found that Zeltiq raised serious questions going to the merits of its claims, the Court now considers whether the balance of hardships tips "sharply" in Zeltiq's favor. *Cottrell*, 632 F.3d at 1132 ("serious questions going to the merits and a hardship balance that tips sharply toward the plaintiff can support issuance of an injunction, assuming the other two elements of the … test [for preliminary injunction] are also met.").

Zeltiq may suffer hardship if an injunction is not issued. Zeltiq devoted resources to obtaining FDA clearance for its CoolSculpting device. Having carved a unique place in the market as the first non-invasive fat reduction device with FDA clearance, Zeltiq stands to lose market share by deceptive advertising which touts other devices as having the same FDA clearance. On the other hand, Zeltiq has not presented any evidence to show that Defendants' promotions of Vanquish actually deceive physicians who purchase the device.

BTL will endure hardship if an injunction is issued. Zeltiq seeks a broad injunction that, in addition to prohibiting promotions which falsely state or imply the Vanquish device is cleared for fat reduction, would also prohibit lawful conduct and impose affirmative obligations. The injunction would require Defendants to de-link the United States website from the non-United States website, and to provide written notification to every physician who has purchased the Vanquish informing them it is not FDA cleared for fat reduction.

Moreover, Zeltiq's requested injunction would prohibit Defendants from selling the Vanquish device for any use that is not FDA cleared, and from working with any physician who employs the Vanquish device for fat reduction. Physicians, however, have the right to use the Vanquish device for fat reduction. Even the Supreme Court has recognized that such off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without

directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). In light of these considerations, the Court does not find that the balance of hardships tips "sharply" in Zeltiq's favor.

D. Whether Zeltiq will Suffer Irreparable Injury if an Injunction is not Issued

Even if the balance of equities tipped sharply in Zeltiq's favor, the Court would still deny Zeltiq's Motion for Preliminary Injunction because of the lack of evidence that Zeltiq will suffer an irreparable injury if an injunction is not issued. This Court has recognized that irreparable harm may result from the "loss of market share." *See Funai Elec. Co., Ltd. v. Daewoo Electronics Corp.*, 593 F.Supp.2d 1088, 1111 (N.D. Cal. 2009) *aff'd*, 616 F.3d 1357 (Fed. Cir. 2010). Nevertheless, Zeltiq has not presented any evidence that it actually lost market share as a result of Defendants' promotion of Vanquish. Zeltiq states in a declaration that BTL has captured some undetermined amount of market share and that "the long-term impact on Zeltiq is difficult to quantify." Altavilla Decl. ¶ 36. This is insufficient.

Zeltiq contends that it may prove a likelihood of irreparable injury by showing evidence "(i) that the parties are competitors in the relevant market, and (ii) that there is a logical causal connection between the alleged false advertising and its own sales position." Reply at 5 (quoting *Euro-Pro Operating LLC dba Euro-Pro Corporation v. Euroflex Americas*, No. 08-6231, 2008 WL 5137060, at *4 (S.D.N.Y. Dec. 8, 2008) (quoting *Zeneca Inc. v. Eli Lilly & Co.*, No. 99-1452, 1999 WL 509471, *36 (S.D.N.Y. July 19, 1999) (quoting *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980)))). In the Court's view, merely showing this logical connection and competition is not sufficient in light of the Supreme Court's 2008 decision in *Winter*, where the Court held that a plaintiff seeking a preliminary injunction must always "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 20 (emphasis in original). Merely showing that the parties are competitors and that there is a logical connection between the false advertising and the plaintiff's sales may be sufficient to show a *possibility* of irreparable harm, but is insufficient to show a *likelihood* of irreparable harm without additional evidence. Accordingly, the Court finds that, even if Zeltiq could prevail on the merits of its claims, Zeltiq has not demonstrated that it is likely to suffer irreparable harm.

* * *

Having concluded that Zeltiq has not shown that the balance of equities tips sharply in its favor or that it will likely suffer irreparable injury if an injunction is not issued, the preliminary injunction cannot be issued. *Winter*, 555 U.S. at 20. The Court need not address whether a preliminary injunction would be in the public interest.

IV. CONCLUSION

For the foregoing reasons, the Motion for Preliminary Injunction is DENIED.

IT IS SO ORDERED.

Dated: March 25, 2014

JOSEPH C. SPERO
United States Magistrate Judge